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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,911	01/07/2002	Frank E. Manning	GUID.038US01	4087

7590 04/13/2004  
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/13/2004

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/041,911

Applicant(s)

MANNING ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 8, 15 and 24 – 31 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,638,268 to Niazi.

In regards to claims 1, 2, 8, 15 and 24 – 31, Niazi discloses applicant's claimed invention including an outer sheath (11) having an open lumen and a pre-shaped distal end (Col. 4, lines 4 – 31); an inner sheath (12) having an open lumen configured to receive a payload, the inner sheath disposed within the open lumen of the outer sheath, the inner sheath being axially rotatably and longitudinally translatable relative to the outer sheath (Col. 3, lines 12 – 15), a distal end of the inner sheath conforming to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assuming a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath (Col. 3, lines 10 – 23; Col. 4, lines 4 – 8); a steering tendon along the outer sheath, a distal end of the tendon connected to a distal tip of the outer sheath (Col. 3, lines 55 - 61); a guide handle connected to a proximal end of the outer sheath; and a steering mechanism (29) pivotably connected to the handle, the steering mechanism connected

Art Unit: 3736

to a proximal end of the tendon and providing a pulling force on the steering tendon to adjust a shape of the preshaped distal end of the outer sheath (Col. 3, line 61 – Col. 4, line 3). Niazi discloses an occlusion device (21) connected to the distal end of the outer sheath (Col. 3, lines 43 – 46). Niazi discloses the outer sheath having a second lumen, the steering tendon disposed within the second lumen of the outer sheath (Col. 3, lines 55 - 59). Niazi discloses the payload comprising a pacing lead configured for implantation with a coronary sinus or branch vessel (Col. 3, lines 29 – 31). Niazi discloses the payload comprising a guide wire and a lead having a lumen dimensioned to receive the guide wire (Col. 5, lines 57 – 64). The open lumen disclosed by Niazi is capable of receiving a payload comprising an injectable media (Col. 4, lines 56 – 58).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claim 1 above, and further in view of U.S. Patent No. 5,409,469 to Schaerf.

In regards to claims 3 and 4, Niazi fails to disclose a longitudinally disposed pre-stress line extending from the proximal end to the distal end of the outer or inner sheath. However, Schaerf discloses a lead introducer having a longitudinally disposed pre-stress line (63) extending from the proximal end to the distal end (Col. 5, lines 25 – 45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by

Art Unit: 3736

Niazi to include pre-stress lines as taught by Schaerf to aid in the removal of the sheath without requiring the sheath to be removed from an end of the lead (Col. 5, lines 25 – 29).

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2001/0039413 to Bowe.

6. In reference to claims 5 and 6, Niazi fails to disclose at least one electrode on the distal end of the inner or outer sheath, and an electrical conductor being coupled to the electrode and being disposed within the inner or outer sheath. However, Bowe discloses a guide catheter having at least one electrode on the distal end of the inner sheath and at least one electrical conductor coupled to the at least one electrode, the conductor being disposed within the inner sheath [0046]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi to include at least one electrode as taught by Bowe in order to provide energy to the tissue to treat different ailments of the heart. Furthermore, it would have been an obvious engineering design choice to place the electrode as disclosed by Bowe on the outer sheath in that the electrode would perform the same function being placed on the outer sheath as well as the inner sheath.

7. Claims 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claim 1 above, and further in view of U.S. Patent No. 6,533,770 to Lepulu et al.

In reference to claims 7 – 10, Niazi discloses an occlusion device being connected to the pre-shaped distal end of the outer sheath (Col. 3, lines 43 – 46). However, Niazi fails to disclose an occlusion device being connected to the inner sheath and at least one pressure sensing device connected to the inner or outer sheath. However, Lepulu et al. discloses a guiding member having

Art Unit: 3736

an occlusion device connected to the distal end of the inner sheath and a pressure sensing device located within the inner sheath (Col. 17, lines 26 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi to include an occlusion device and a pressure sensing device as taught by Lepulu et al. in order to further the diagnostic capabilities of the device. Furthermore, placing the occlusion device and the pressure sensing device on the inner or outer sheath is a design consideration within the skill of the art.

8. Claims 11 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claim 1 above.

In regards to claims 11 and 12, Niazi discloses the outer sheath having a substantially circular curve proximally adjacent to a strait section, the curve having a bend radius ranging from about 0 degrees to about 180 degrees and a bend radius from about 1 cm to 7 cm. Niazi discloses the inner sheath having a substantially circular curve proximally adjacent to a strait section, the curve having a bend radius ranging from about 0 degrees to about 150 degrees and a bend radius from about 1 cm to 5 cm (Col. 4, lines 4 – 23). However, Niazi fails to disclose the tip of the outer sheath having a length of about 1 cm to 5 cm and the tip of the inner sheath having a length of about 0.5 cm to about 4.0 cm. Niazi teaches that the predetermined shape and size of the curve can be changed to accommodate different heart sizes (Col. 4, lines 25 – 31). It would have been obvious to modify the size and shape of the predetermined curves as needed to accommodate different heart sizes as taught by Niazi.

In reference to claims 13 and 14, Niazi discloses the tendon being disposed along the outer sheath (Col. 3, lines 55 – 59), but fails to disclose the tendon being on outer surface of the sheath or within the open lumen of the sheath. However, due to the lack of criticality in the specification for

Art Unit: 3736

the positioning of the steering tendon, it would have been obvious to one having ordinary skill in the art at the time the device was made to position the tendon on the surface or within the interior of the lumen as desired.

***Response to Arguments***

9. Applicant's arguments filed 1/20/04 with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,408,214 to Williams et al. shows the general state of the art in regards to guide catheters having inner and outer lumens with pre-shaped distal ends.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
JMLF

April 7, 2004



**ERIC F. WINAKUR  
PRIMARY EXAMINER**